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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,265	03/02/2004	Joseph Francis Paraschac	7048USO1	2815
23492	7590	05/03/2007		
ROBERT DEBERARDINE ABBOTT LABORATORIES 100 ABBOTT PARK ROAD DEPT. 377/AP6A ABBOTT PARK, IL 60064-6008			EXAMINER KOTINI, PAVITRA	
			ART UNIT 3731	PAPER NUMBER
			MAIL DATE 05/03/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

e1

Office Action Summary	Application No. 10/791,265	Applicant(s) PARASCHAC ET AL.	
	Examiner Pavitra Kotini	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2007.
 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-11,13,14 and 16-20 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 1,2,4-11,13,14 and 16-20 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☒ The drawing(s) filed on 02 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3/2/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of species II in the reply filed on 3/2/07 is acknowledged.

Drawings

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the informal figures 10-13 are not of sufficient quality to permit proper examination. For instance, shaft 407 cannot be depicted in figure 11. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Objections

Claims 5, 8, 10, 11, 12, 19, and 20 are objected to because of the following informalities: subject matter in the parenthesis should be either removed or incorporated in the claim without parenthesis. The subject matter within the parenthesis has not been given any patentable weight. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

Art Unit: 3731

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the feature of "a biocompatible coating" is not disclosed in the specification.

Claims 13, 14, and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The above listed claims stem off of cancelled claim 12, so it is unclear whether claim 13 is dependent on claim 11, 10, or independent claim 1.

Claims 5, 8, 10, 11, 12, 19, and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-11, 14, 16-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al. (US-5480403).

Lee discloses a device for closing an opening formed in a vessel, the device comprising:

Regarding **claim 1**, an anchor (111) deployable within a blood vessel lumen (150); at least one barb member (122 and 123) having an undeployed position (fig. 1) and a deployed position (fig. 3), wherein the barb member is moved to the deployed position when tension is applied to the device (col.3, line 62- col.4, line 101); and a body member (121) extending between the anchor (111) and the barb member (122 and 123).

Regarding **claim 2**, a plug (112) disposed on the body member.

Regarding **claim 4**, the device further includes a shaft (passageway defined by 128) extending from said anchor (111) to said barb member (122).

Regarding **claim 5**, the device further includes a tether (101).

Regarding **claim 6**, the device is constructed of a bioabsorbable material (col.4, lines 25-26).

Regarding **claim 7**, it is old and well known in the art that the closure device is made from a material consisting of: stainless steel, titanium, nitinol, plastic and ceramic. For example, see US patents 20040034357, 5980559, 5236445, 20040199165, 20020188318, and 6447546.

Regarding **claim 8**, the body member of the device is manufactured from lactide (col.4, lines 25-29; polylactic acid is a polymerized form of lactide).

Regarding **claim 9**, it is old and well established in the art that medical devices inserted into the body can be coated with a biocompatible coating. For example, see US patent 6838493 and 5505736.

Regarding **claim 10**, the introductory statement of intended use: " for closing an opening formed in a vessel or artery", has been carefully considered but deemed not to impose any structural limitations on this apparatus claim. The prior art's device is capable of being used as claimed if one desires to do so.

The device comprising: an anchor portion (111); a plug portion (112) extending from said anchor portion; and at least one barb member (122) disposed proximal (114) to said anchor portion.

Regarding **claim 11**, at least one barb member (122) is movable between a first and second position (fig. 1-3; col.3, line 62- col.4, line 101), wherein said second position (fig. 3) of said at least one barb member (122) is generally orientated outwardly (arrows in fig. 3) from said plug portion (112).

Regarding **claim 14**, said barb member moves from a first position (unactivated state as depicted in fig. 1) to a second position (activated state, fig. 3) in response to said force (pulling suture 101) and movement of the device (112 moves proximally and urges barbs 122 to extend radially outward; col.4, lines 4-8).

Regarding **claims 16 and 17**, the barb member (122) in the deployed position ("activated state"; col. 3, lines 15-20) has a greater width than in the first position (fig. 3).

Regarding **claim 18**, a main plug body having a generally cylindrical shape (fig. 1, 112; col.3, lines 23-25); and at least one barbed member (122) extending from said

main plug body (112), wherein said barb member is radially movable between a first and a second position (col.3, lines 53-55).

Regarding **claim 19**, an anchor portion (111) extending from said plug (112; col.3, lines 23-25).

Regarding **claim 20**, said at least one barbed member (122) is movable between a first and a second position (figs. 1-3) and configured to move said barb member between said first and second position (col.3, line 62- col.4, line 101).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (US-5480403) in view of Ginn (US-20020072768).

Lee discloses the invention substantially as claimed above, but fails to disclose an introducer sheath. However, Ginn teaches how an introducer sheath may facilitate introduction of various devices into a vessel (para.0003). Since it is old and well known in the art to include an introducer sheath when inserting a device into a body lumen, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the closure device of Lee to include an introducer sheath. Such a modification would minimize trauma and bleeding (para.0003).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pavitra Kotini whose telephone number is 571-272-0624. The examiner can normally be reached on M-F 8:30am to 6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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SUPERVISORY PATENT EXAMINER *nc*
4/20/07